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(00543-22)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	<b>BEFORE THE BOARD OF PATENT</b>
	)	<b>APPEALS AND INTERFERENCES</b>
Boris P. Kovatchev et al.	)	
	)	Appeal No.:
Serial No. 10/524,094	)	
	)	Examiner: L. Clow
Filed: February 9, 2005	)	
	)	Group Art Unit: 1631
For: Method, system, and computer	)	
program product for the processing	)	
of self-monitoring blood glucose	)	
(SMBG) data to enhance diabetic	)	December 7, 2010
self-management	)	

**REPLY BRIEF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

This is a reply under 37 CFR § 41.41 to the Examiner's Answer dated October 7, 2010 (the "Answer"). The indication in the Answer that claims 20 – 22, 25 – 36, 39, 113 – 119, 121, 125 – 134, 156 – 158, 161, 165 – 174, 176 – 178, 181, 185 – 194, 216 – 218, and 222 – 224 would be allowable if rewritten in independent form is noted.

## ARGUMENT

### **The Rejection of Claims 1 – 18, 112, 113, 135 – 154, and 195 - 214 Is Improper**

The Answer improperly relies on the “*Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos*,” (75 FR 43922),

(“Guidance”) as support for the rejection of claims 1 – 18, 112, 113, 135 – 154, and 195 – 214 under 35 U.S.C. § 101.

In particular, the Answer misapplies the Guidance as an exclusive test instead of general guidelines to be used in accordance with controlling judicial precedents. In attempting to apply the Guidance the Answer erroneously focuses only on what the claims allegedly do not state or do not include instead of evaluation of the claims as a whole.

As explained in the main brief, the United States Supreme Court has ruled that the “machine-or-transformation test” is not the exclusive test for determining whether claims are directed to statutory subject matter. Bilski v. Kappos, Slip Opinion, June 28, 2010, p. 7 (“The Court is unaware of any “ordinary, contemporary, common meaning,” *Diehr, supra*, at 182, of the definitional terms “process, art or method” that would require these terms to be tied to a machine or to transform an article.”)

The appealed claims in this case clearly are not directed to abstract intellectual concepts but to the contrary, the appealed claims are directed to a specific method of estimating the glycosylated hemoglobin of a patient and communicating the estimate to a user, are directed to a method that pertains to analysis of quantitative physical characteristics of a physical patient, and that has practical application in the prevention or treatment of an adverse physical condition of a patient. Thus, under Bilski v. Kappos, the claims represent statutory subject matter.

Relying on the Guidance, the Answer states that the claims are not patent-eligible because they allegedly do not include “an express or inherent recitation of a specific machine to perform the method of evaluating the HbA1c of a patient.” Answer at 5. This conclusion is legally erroneous, because it is directly contradictory to the U.S. Supreme Court’s ruling that there is no requirement that a process or method “be tied to a machine.” Bilski v. Kappos, *supra*. Since under the controlling judicial precedent there is no requirement that method claims “include an express or inherent recitation of a specific machine to perform the method” as alleged in the Answer, the Answer’s conclusion that the claims are not patent-eligible for this reason, is erroneous as a matter of law.

The Answer further states, incorrectly, that the claims “merely recite mathematical concepts of manipulating data by preprocessing data to convert it to a derived data, estimating the HbA1c from a predetermined formula, and validating the estimate without the recitation of a machine in which to perform such steps.” Answer at 5.

Again, requiring the claims to incorporate a “the recitation of a machine in which to perform such steps” is contrary to the controlling Supreme Court precedent and thus such requirement cannot be legally sustained. Further, the claims do not “merely recite mathematical concepts.” As explained above, the claims considered as a whole are directed to a specific method of estimating the glycosylated hemoglobin of a patient and

communicating the estimate to a user, which pertains to analysis of quantitative physical characteristics of a physical patient, and that has undisputed practical application in the prevention or treatment of an adverse physical condition of a patient. It is incomprehensible how the claims could be said to be directed only to “general mathematical concepts.”

Finally, the Answer alleges that the claimed step of electronically transforming the estimate into a visual depiction that is outputted to a user “is not material to or central to the purpose of the claimed subject matter and does not constitute a transformation to a different state or thing.” Answer at 5, 8 – 10. This statement is in error for at least two reasons.

First, the purpose of the claimed invention is to evaluate the glycosylated hemoglobin (HbA1c) of a patient and to communicate that evaluation to a user, so that appropriate treatment of the patient may be performed in accordance with the evaluation. If the result of evaluation were not communicated to a user, then the invention would serve no function because no one would know what the result of evaluation was and a user could not act on information that was unknown.

Second, notwithstanding the Supreme Court’s ruling that a method claim is not required to “transform an article,” Bilski v. Kappos, *supra*, existing and undisturbed Federal Circuit precedent establishes that electronically transforming data that is representative of physical parameters in the real world so that it may be displayed to a

user, does in fact constitute a “transformation” as that term has been applied to the determination of whether a method claim passes statutory muster.

In Bilski, the Federal Circuit explained that the “transformation” part of the test is met where the data represents physical and tangible objects, and electronic transformation of data into a visual depiction is set forth:

In contrast, we held one of Abele's dependent claims to be drawn to patent-eligible subject matter where it specified that "said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner." Abele, 684 F.2d at 908-09. This data clearly represented physical and tangible objects, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible.

We further note for clarity that the electronic transformation of the data itself into a visual depiction in Abele was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented. We believe this is faithful to the concern the Supreme Court articulated as the basis for the machine-or-transformation test, namely the prevention of pre-emption of fundamental principles. So long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle.

88 USPQ2d at 1397.

Here, the claims all set forth electronic transformation of the estimate data into a visual depiction that is presented to a user, and thus, satisfies the “transformation” test as enunciated in In re Bilski, a part of the Federal Circuit’s ruling that was not reversed

by the Supreme Court and which thus constitutes binding legal precedent. The position of the Answer is contrary to the holding of the Federal Circuit and thus is legally unsustainable.

**The Rejection of Claims 6, 8 – 10, 24, 26 – 28, 120, 122 – 124, 140, 142 – 144, 160, 162 – 164, 180, 182 – 184, 200, 202 – 204, 220 and 226 as Being Indefinite Is Improper**

The rejection of claims 6, 8 – 10, 24, 26 – 28, 120, 122 – 124, 140, 142 – 144, 160, 162 – 164, 180, 182 – 184, 200, 202 – 204, 220 and 226 under the second paragraph of 35 U.S.C. § 112 as being indefinite, is improper and should be reversed.

The Answer alleges that claim 6 merely recites definitions of claim terms and not mathematical formulae. In response, it is again pointed out that claim 6 explicitly defines RiskLO and RiskHI, for example: RiskLO=Risk1 if (BG is less than about 112.5), otherwise RiskLO=0; Risk1 = 22.765(Scale)<sup>2</sup>; and Scale=[ln(BG)]<sup>1.0845</sup> – 5.381, wherein BG is measured in units of mg/dl. This is an “actual” mathematical formula and is definite under 35 U.S.C. 112. The recitations of claim 6 fully define how both the Low Blood Glucose Index and High Blood Glucose Index are computed. Further, claim 6 must be interpreted in light of the specification and not in a vacuum, and when so interpreted does particularly point out and distinctly claim the subject

matter regarded as the invention. This ground of rejection therefore should be reversed.

**The Rejection of Claims 1, 19, 37, 38, 135, 155, 175, 195, 215 and 221 Under 35 U.S.C. § 102(e) as Being Anticipated By Heinonen Is In Error and Must Be Reversed**

Heinonen discloses a method of predicting HbA1c by developing a model that correlates measured blood glucose levels with correspondingly measured HbA1c levels. See Fig. 1. When subsequent blood glucose measurements are taken, they are applied to the model to obtain a corresponding predicted HbA1c level. In other words, Heinonen discloses the generation of a sort of HbA1c “look-up table” where a set of blood glucose measurements is associated with a corresponding set of HbA1c measurements taken at the same time as the blood glucose measurements. See col. 4, line 66 – col. 5, line 9. The “look-up table” is periodically updated as new HbA1c measurements are made. Col. 6, lines 17 – 21.

Heinonen does not pre-process collected BG data to convert the collected BG data into derived BG data derived from the collected BG data; estimate HbA<sub>1c</sub> by applying at least one predetermined formula to said derived BG data; validate the estimate via sample selection criteria; electronically transform the estimate into a visual depiction; or output the visual depiction of the estimate to a user as required by the claims on appeal.

The Answer alleges that Heinonen derives a mathematical model of the behavior of the HbA1c component level relative to the BG level using previously measured BG levels. This derivation of a mathematical model of HbA1c behavior using previously measured BG levels does not correspond to the claimed pre-processing collected BG data to convert the collected BG data into derived BG data derived from said collected BG data, estimating HbA1c by applying at least one predetermined formula to said derived BG data, validating the estimate via sample selection criteria; electronically transforming the estimate into a visual depiction; and outputting the visual depiction of the estimate to a user. As explained at col. 6, lines 1 – 45, Heinonen predicts a current level of HbA1c based on past correlations of actual HbA1c measurements with actual blood glucose measurements, using regression coefficient model vectors as set forth in Equation (5). In contrast, the claimed invention evaluates HbA1c based on conversion of collected BG data to derived BG data and application of a predetermined formula to the derived BG data.

The Answer fails to set forth a *prima facie* case of anticipation. The Answer alleges only that Heinonen “teach a method and system whereby levels of HbA1c are predicted using a mathematical model which is derived to predict the behavior of Hb1c relative to blood glucose (abstract, column 2, lines 20 -53), therefore meeting the limitations of converting BG data and estimating HbA1c and providing an output of the data (Figure 6).” The claims on appeal, however, do not claim predicting levels of



HbA1c using a mathematical model which is derived to predict the behavior of HbA1c relative to blood glucose as alleged in the Answer. The rejection is improper and must be reversed.

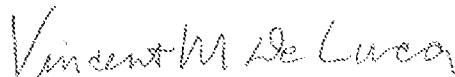
**CONCLUSION**

In view of the foregoing and the arguments presented in the main brief on appeal, claims 1 – 39 and 112 – 226 are submitted to be directed to a new and unobvious method, system and computer program product for evaluation of the glycosylated hemoglobin of a patient, which is not taught by the prior art and which fully comply with the statutory category of invention and definiteness requirements of the patent laws. The Honorable Board is respectfully requested to reverse all grounds of rejection and to direct the passage of this application to issue.

Please charge any fee or credit any overpayment pursuant to 37 CFR 1.16 or 1.17 to Novak Druce Deposit Account No. 14-1437.

Respectfully submitted,

NOVAK, DRUCE, DELUCA + QUIGG LLP



By \_\_\_\_\_

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